Healthcare Improvement (HCI) Initiative

Call for Grant Applications (CGA)

Lilly USA, LLC
Lilly Corporate Center
Indianapolis, Indiana 46285
U.S.A.

CGA Identifier: HCI- 0011
Due Date: 3/20/26

Introduction

Lilly is committed to supporting Healthcare Improvement (HCI) initiatives that foster the translation of scientific evidence into evidence-based routine clinical practice using improvement/implementation science theory, processes, and models to ultimately improve the safe, effective, efficient, equitable, and timely delivery of optimal patient care.* Healthcare improvement is used as an umbrella term to include Quality Improvement (QI), Improvement/Implementation Science, and applicable Health Services Research with aims aligned to those outlined above.

Lilly is requesting proposals that seek to objectively measure and systematically improve the quality of healthcare by identifying gaps and root causes, and designing, testing and measuring strategies/interventions that yield improved outcomes for patients and healthcare systems.** The proposal should outline how the initiative can effectively address systemic barriers (i.e., ones associated with multi-disciplinary teams, health system, data, and care delivery processes) and objectively measure impact on processes and/or patient outcomes.

Lilly seeks to support initiatives that demonstrate sustainability and scalability with the potential for widespread transferability and dissemination to other healthcare organizations (e.g., based on insights from Implementation Science, and/or or using IS methods).

Lilly shall not be involved in any aspect of project development nor the conduct or execution of the initiative. Lilly does not support initiatives or medical activities, for the purpose of encouraging off-label use of our products. It is not the intent of this CGA to support clinical research projects evaluating novel therapeutic or diagnostic agents.

Process

Interested parties are invited to submit a full proposal to this CGA using the online portal. Please read through this CGA first then review and answer the question prompts for the online portal.

**CMS AHRQ / **IHI Don Berwick*

Preference will be given applicants who are committed to improving the care of patients at scale, including large integrated health delivery systems, (inter)national medical societies and professional associations, and groups of collaborating/partnering health systems. Proposals that include collaboration and/or partnerships between organizations are encouraged. Multi-supported proposals will be accepted.

Lilly does not provide funding to individuals or solo medical practices.

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PLEASE READ THIS DOCUMENT IN ITS ENTIRETY AND ENSURE THAT YOUR PROPOSAL INCLUDES ALL OF THE REQUESTED INFORMATION. INCOMPLETE PROPOSALS MAY NOT BE FORWARDED TO THE REVIEW COMMITTEE FOR CONSIDERATION.

1. Purpose: Lilly is currently seeking HCI Initiative proposals to improve the care of people living with early symptomatic Alzheimer's disease (Mild Cognitive Impairment (MCI)due to Alzheimer's disease (AD) or mild dementia due to AD)

Evidence demonstrates the following healthcare gap:

Although Amyloid-targeting therapies have demonstrated clinical benefit in early Alzheimer's disease (AD) when initiated promptly after biomarker confirmation, real-world implementation reveals substantial delays between diagnosis and treatment initiation. Recent real-world data show that even in specialized centers, the process from referral to treatment can take several months, often exceeding the optimal therapeutic window suggested by clinical trials, which emphasize early intervention for maximal benefit. Recent U.S. practice data report a median time of approximately 4.9 months from earliest AD diagnosis to first infusion, while case reports from specialized clinics indicate delays of up to 20 months from initial presentation to treatment initiation**.** Addressing these delays through streamlined diagnostic pathways, expanded biomarker access and optimized care coordination models is essential to realize the full benefit of Amyloid-targeting therapies in AD.[1-11]

There are opportunities to improve processes and remove barriers in the health care system to ensure that appropriate patients who may benefit from Amyloid-targeting therapy receive timely and optimal evidence-based care including

- Safe and seamless care coordination among the multi-disciplinary team, including (where appropriate) timely referrals to dementia specialists
- Appropriate and timely selection for therapy (including a clinical diagnosis of MCI or mild dementia due to AD and a biomarker confirmation of amyloid pathology)
- Timely initiation of therapy for appropriate patients according to approved prescribing information

Lilly is requesting proposals for an HCI project that seeks to decrease the time from biomarker confirmed diagnosis of MCI or mild dementia due to AD to initiation of amyloid-targeting therapy in appropriate patient according to approved prescribing information.

2. Budget: The budget related to this CGA is approximately $400,000 – 600,000 per project.

Multiple Individual initiatives of varying budget will be considered and evaluated and may be distributed among more than one applicant. The amount Lilly will fund will depend upon the evaluation of the proposal and costs involved, and this amount will be stated clearly in a formal Letter of Agreement.

Institutional overhead and indirect costs ("overhead") may be included within the funding request. However, any included overhead should be kept to a minimum, may not exceed 30% of the total request, and may not cause the amount requested to exceed the budget limit set forth in the CGA. For institutions with actual overhead rates under 30%, do not increase the funding request to the maximum allowed. NOTE: funding may not be used for entertainment, capital, gifts (monetary or otherwise), or personal travel.

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For associated HCI proposal budget submission, please see grant submission requirements guidance document in the portal resource library, and include this documentation when you submit your proposal

3. Health System Practice Gap(s): The applicant must describe the health system practice gaps and objective data sources that were used, or will be used, to measure gaps in processes, patient care, and outcomes at baseline and at the conclusion of the initiative. ***Preference will be given to proposals that have already undertaken baseline measurement of the gap with the target system(s) using objective measures (e.g., data for EHR, direct observation, etc.)***

4. Root Causes and Barriers: The applicant must describe the processes and methods that were used, or will be used, to identify the root causes underlying the targeted Health System Practice Gaps that are preventing optimal patient outcomes.

Literature suggests that some potential root causes underlying these gaps include:

- Lack of workflows and processes for identification of the appropriate patient for therapy – including cognitive assessments, biomarker testing and APOE testing [12,13]
- Lack of optimal care coordination and communication with essential multi-disciplinary team members to ensure safe and seamless coordinated care (i.e., referring clinicians, imaging physicians, and other professionals as applicable). [14,15]
- Lack of access to specialty care and diagnostic and delivery tools (i.e., imaging, biomarker testing, and infusion centers). [12,15,16]
- Lack of practice infrastructure (including workforce and staffing) to manage increased referrals, timely patient evaluation, oversight of infusion therapy, and necessary monitoring with serial MRIs [12,15,16]
- Lack of processes to navigate insurance and reimbursement complexities [12,15,16]

These literature-based root cause(s) may or may not be relevant to the specific system(s) targeted in your proposal. It/they is/are provided as an example(s) for consideration. It is not expected that this/these will be addressed in the HCI initiative. Each system must identify and address root causes of the greatest relevance and potential impact.

Preference will be given to proposals that:

1) use respected and standard root cause methods as recommended by the Institute for Healthcare Improvement (IHI) and Agency for Healthcare Research and Quality (AHRQ) etc.
2) may already have evidence-based insights into the root causes of relevance to the system.

5. Strategy/Intervention(s): It is Lilly's intent to support an initiative that will lead to timely and measurable improvements in time from biomarker confirmed diagnosis of MCI or mild dementia due to AD and initiation of amyloid-targeting therapy in appropriate patients according to approved prescribing information

The applicant should describe in detail the planned strategy/intervention(s), the rationale, and the implementation plan.

If the root causes have not yet been identified, it is not possible to design an effective intervention. Therefore, if root causes have not been identified, the applicant should clearly describe the approach and methods that will be used to design and implement an effective strategy/intervention(s) to address

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the identified root causes, including the roles and responsibilities of all individuals who will be responsible for designing and implementing the strategy/intervention(s).

6. Outcomes Measures: All proposals should include detailed description of all the objective outcomes measures that will be used to measure the impact of the strategy/interventions. The improvement/implementation science framework(s) used for the measurement plan should be clearly outlined, along with the measures selected.

To strengthen alignment with the aim of this CGA, applicants are encouraged to include the primary outcome measure below in addition to initiative-specific measures deemed important. Final measures will be determined by the applicant.

Primary

- Time from biomarker confirmed diagnosis of MCI or mild dementia due to AD to initiation of Amyloid - targeting therapy in appropriate patients according to approved prescribing information*

Secondary

- % change of patients evaluated for therapy who receive appropriate cognitive assessments and biomarker testing using appropriate tools per approved prescribing information and appropriate use recommendations
- % change of appropriate patients with MCI or mild dementia due to AD d receive *APOE* testing based on prescribing information
- % change of appropriate patient referrals to dementia specialists for diagnostic follow-up and/or evaluation for treatment
- Time from referral to specialist to initiation of therapy

*Preference will be given to proposals that include an analysis of the impact of type of biomarker testing (e.g., PET vs blood) on time to initiation of therapy

Preference will be given to proposals that include a realistic estimate of the expected magnitude of improvements.

Outcomes measures used to measure the impact of this initiative should not be directly aligned with measures for which you (or participating system/clinics/practices) are already being incentivized or rewarded by a federal government program (e.g., CMS quality programs)

7. Initiative Timing: Ideally, program will launch Q2 2026 with a project length of 12-18 months. Interim report/read out is expected quarterly and long-term sustained results should be reported as appropriate to the setting and the initiative.

Please explain the rationale for suggested start/end dates, duration of the program and timeline for reporting any long-term results.

8. Geographic Scope: US

9. Qualification and Eligibility:

- Provide information on the qualifications and experience of the project leader and collaborators and include any certifications (i.e., Black Belt, Science of Improvement training, implementation science

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certification), recognitions (ex: Baldridge award) and the number and type of HCI projects you or your organization have successfully executed in the past.

- Provide a robust example of a past completed HCI project.
- Explain any methods that will be used to ensure those expected to participate are fully trained in the program expectations and any skills that may be needed to ensure effective execution of the project.
- If you are not in direct control of the data used for measurement, please provide letters of commitment from those with direct control of data indicating full support to participate and to supply data to measure baseline and outcomes measures in a timely manner.
- If you are not in direct control of the personnel and clinicians who will likely be involved in implementing changes, please provide letters of commitment to ensure their full and timely participation from appropriate leaders in your organization.

10. Communication/Publication Plan: Include a description of how the results of this initiative will be presented, published, or disseminated.

11. Sustainability Plan: Include a description of how, if this initiative is successful, it will be ensured that the positive outcomes will be sustained once the funding received from this proposal has ended, e.g. by integrating within routine clinical practice.

Please note that continued measurement of key outcomes outlined in section 6 is expected, including a meeting ~12-month post-initiative closing to discuss the sustained impact of the initiative on the target outcomes.

12. Scalability: Include a description of, if this initiative is successful, potential plans to take effective healthcare practices from one setting and apply them both within the pilot health system(s) (e.g., more clinics/sites) and beyond (e.g., other systems).

Preference will be given to applicants who have the ability and interest to create generalizable insights and guidance for further implementation of successful change interventions. Collaborations with other health systems to ensure scaling beyond the pilot health system(s) is encouraged).

13. Mandatory Submission Instructions & Requirements:

- To ensure appropriate routing of your proposal – please ensure you select yes for the question “Is this grant in response to a CGA” and select the unique identifier provided at the top of this document
- Please limit the length of the proposal to **20 pages or less** (not including references and budget).
- Please be prepared to provide progress and impact updates to Lilly at least quarterly, and to meet with Lilly and any other involved parties at initiative kick-off and closing (additional guidance to be shared with funded organizations/institutions), and ~12-months post initiative closing
- All responses to this HCI CGA are to be submitted online to https://grantoffice.lilly.com/ by 3/20/2026.. **For proposal application and portal questions, please contact lillygrantoffice@lilly.com**

We look forward to your response.

Linda Battiato

Healthcare Improvement Hub

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SPECIFIC REFERENCES FOR THIS CGA

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